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Massachusetts Board of Registration in Pharmacy

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1. New Board Member Announcement

On May 18, 2004, Governor Mitt Romney appointed Steven Budish to serve a five-year term as a public member of the Massachusetts Board of Registration in Pharmacy. Mr Budish is an avid pilot and chief executive officer of a large dental clinic in Worcester, MA.

2. Donna Horn President of NABP

At the National Association of Boards of Pharmacy® (NABP®) 100th Annual Meeting and Centennial Celebration in April, Donna Horn, RPh, past president of the Massachusetts Board, was elected 100th president of NABP. Following a very busy year as president of NABP, Donna will become chairperson of NABP's Executive Committee for the period of 2005-2006.

3. From the President's Desk

James T. DeVita, RPh, President

It is our mission at the Board of Pharmacy to promote, preserve, and protect the health, safety, and welfare of the citizens of the Commonwealth by fostering the delivery of quality pharmaceutical care. To accomplish this mission, the Board must assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and open communication.

The theme of this month's *Newsletter* is patient safety and dispensing accuracy. Promoting patient health and safety through accurate dispensing are of utmost importance to pharmacists. To achieve these goals, we must continuously seek to improve our profession and how we deliver our services. Every pharmacist and pharmacy should have the desire to persistently monitor, assess, and improve their practice and practice setting. Many pharmacists and pharmacies have embraced quality and have structured programs well underway; others are in the formative stages.

Safety improvement and preventative measures can take on many forms: workflow, technology, lighting, education, training, and staffing. Two of the simplest preventative measures are communication and awareness.

This month, we bring focus to two important safety issues: counterfeit drugs and look-alike/sound-alike drugs. The most effective way to address each of these concerns is to raise awareness and communicate an understanding as to the subtle nature of these challenges. The Board has developed and published guidelines to assist you and your pharmacy staff in managing these and other issues. Visit our Web site and review the section on Best Practices.

4. Best Practice Recommendation of the Month Addresses Counterfeit Drugs

In the April 2004 *Newsletter* the Board wrote,

> On February 18, 2004, United States Department of Health and Human Services Secretary Tommy G. Thompson, Food and Drug Administration (FDA) Commissioner Mark McClellan, and NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, held a joint press conference to announce FDA's Task Force Report on counterfeit drugs, "Combating Counterfeit Drugs" (www.fda.gov/oc/initiatives/counterfeit/report02_04.html). NABP and FDA have joined forces in dealing with this emerging threat and NABP has developed new model regulations for the licensing of drug wholesalers that NABP and FDA are asking member boards of pharmacy to adopt. These model regulations will require appropriate background checks of key employees and electronic tracking requirements by 2007, called "pedigrees," which will trace the movement of prescription drugs from manufacture to dispensing. NABP will also develop a clearinghouse of information on these wholesalers and has provided a list of drugs most suspected of being copied by clandestine operations. For further information, visit NABP's Web site at www.nabp.net.

The Board also described the 21 Best Practice Recommendations developed in 2003, which the Board believes may assist in reducing medication errors, improving the quality of drug delivery, and optimizing patients' outcomes (these recommendations may be found on the Board's Web page at www.state.ma.us/reg/boards/ph/misc/bprac.htm).

In response to recent issues regarding counterfeit drugs finding their way into the marketplace, the Board voted to adopt a best practice recommendation for pharmacies regulated by the Board.

Best Practice Recommendation #22 – Develop and implement written policies and procedures regarding the receipt, storage, and security of controlled substances.

Recommended Actions:

- Visually examine all deliveries promptly on receipt to identity contents and determine if any contaminated, damaged, misbranded, expired, and/or suspected counterfeit drugs or devices are included in the shipment.
- Quarantine any drugs or devices found to be unacceptable for further examination and determination.
- Inspect medication during final verification to assure product accuracy and integrity.
- Request wholesalers to certify that all medications delivered to the pharmacy, not accompanied by a pedigree, are purchased directly from the manufacturer.
- Report suspected counterfeit medications to MedWatch (the FDA safety information and adverse event reporting program), the Board, and appropriate law enforcement authorities within three business days.
- Educate consumers about the risks of counterfeit medications:
  - Encourage consumers to promptly consult with health care professionals if they suspect that their medication is counterfeit.

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FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug and Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretative rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of

Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National List Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drugs Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

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- Remind consumers to be aware of noticeable differences in their medications or packaging and the occurrence of any adverse events.
- Alert consumers of the important role pharmacists play in identifying, reporting, and responding to counterfeit drug events.
- Advise consumers to make online medication purchases from pharmacies that have obtained the Verified Internet Pharmacy Practice Sites™ Seal from NABP.

♦ Maintain records of counterfeit reports from manufacturers and other sources for a minimum three-year period.
♦ Consult NABP's "National Specified List of Susceptible Products" available for reference at www.nabp.net and the Board's Web site under "Board News" at www.mass.gov/reg/boards/ph.

5. Mix-ups in Zantec/Zyrtec

By Karen Ryle and Donna Horn

In Massachusetts, as well as other parts of the country, there have been numerous errors that have occurred in the pediatric population where **Zantac®** (ranitidine) syrup (Glaxo Wellcome) has been prescribed but **Zyrtec®*** (cetirizine) syrup (Pfizer) has been dispensed. Zantac is an H2 receptor blocker and Zyrtec is an H1 antihistamine. Although these medications do not have overlapping dosage strengths, both are available in the syrup dosage form: Zantac as 150 mg/10 mL and Zyrtec as 5 mg/5 mL. Since a different company manufactures each drug, the container labels look dissimilar. However, the syrups of both drugs are available in 480 mL amber glass bottles. Zyrtec syrup is also available in a 120 mL bottle. The proprietary names look and sound alike, increasing the potential for medication errors.

Errors occurred most frequently in patients ranging in ages from seven days to 15 months. In one case, a 12-month-old male patient was prescribed 120 mL of Zantac syrup but was given 120 mL of Zyrtec. The error occurred when the incorrect stock bottle of Zyrtec syrup was chosen by the technician and poured into the dispensing bottle labeled as Zantac. The mother noticed that the baby became "violently ill," but the doctor did not find any serious injury after examining the baby. In another case, a 15-month-old patient was given Zyrtec instead of Zantac for six weeks before the error was discovered. The patient's reflux-induced sinusitis continued until the error was corrected. Other patients experienced sleep disturbances, increased thirst, decreased appetite, diarrhea, vomiting, and weight loss as a result of the errors. Thankfully, none of the symptoms caused serious harm to patients.

Safe Practice Recommendation

♦ Separate stock bottles of Zantac and Zyrtec syrups in pharmacy dispensing areas and any other areas in the health care facility where the drugs are stored* (eg, automated dispensing cabinets).
♦ Encourage prescribers to include the drug's indication to differentiate these look-alike drug names and reduce the risk of selecting the wrong drug due to poor handwriting.*
♦ As with all liquid oral medications, physicians should include the desired mg/mL concentration to guide proper drug selection, especially since the drug concentrations differ.*
♦ The dose should also be expressed in mg, not just volume (mL or teaspoonfuls). Place reminders on stock bottles and install pharmacy computer alerts to advise staff of the risk for errors.*
♦ It is also helpful to warn patients about the risk of confusing these two products so they can detect possible errors when filling prescriptions.
♦ As a final check, immediately before the patient or caregiver leaves the pharmacy department with the filled prescription, open the bottle and sniff the liquid. Does it smell like mint? If so, then it must be Zantac. What does the label indicate it is supposed to be?

**Institute for Safe Medication Practices. Action needed to prevent dangerous Zyrtec-Zyprexa mix-ups.* ISMP Medication Safety Alert! *Volume 5, Issue 22, November 1, 2000.*

**Similar sound-alike, look-alike mix-ups have occurred with Zyrtec and Zyprexa® tablets – be mindful.*

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